



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 13 1999

NDA 18-705/S-008

G. Pohl Boskamp GmbH Co.
c/o GloboMax LLC
Attention: David Young, Pharm.D., Ph.D.
7250 Parkway Drive, Suite 430
Hanover, MD 21076

Dear Dr. Young:

Please refer to your supplemental new drug application dated November 9, 1998, received November 12, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrolingual (nitroglycerin lingual aerosol) Spray.

This supplemental new drug application provides for final printed labeling revised by, adding the following in bold print as the first paragraph of the **WARNINGS** section of the labeling:

Amplification of the vasodilatory effects of Nitrolingual by sildenafil can result in severe hypotension. The time course and dose dependence of this interaction has not been studied. Appropriate supportive care has not been studied, but it seems reasonable to treat this as a nitrate overdose, with elevation of the extremities and with central volume expansion.

In addition, the following paragraph has been added under **PRECAUTIONS**:

INFORMATION FOR PATIENTS: Physicians should discuss with patients the contraindication of Nitrolingual Spray with concurrent sildenafil (Viagra).

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your November 9, 1998 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research